K130016

SECTION 5: 510(K) Summary

FEB 05 2013

Submitter:	LeMaitre Vascular, Inc. 63 Second Avenue Burlington, MA 01803
Contact Person:	Xiang Zhang Director of Regulatory Affairs Phone: 781-425-1729 Fax: 781-425-5049 Email: xzhang@lemaitre.com
Date Prepared:	January 2, 2013
Trade Name:	LifeSpan ePTFE Vascular Graft
Common Name:	Vascular graft prosthesis
Classification Name:	Prosthesis, Vascular Graft
Predicate Devices:	Baxter reinforced expanded PTFE vascular graft (K933590); Baxter reinforced expanded PTFE stepped vascular graft (K944844); Baxter ePTFE externally supported vascular grafts (K944858); LifeSpan reinforced ePTFE straight, externally supported, stepped vascular grafts (K032900)
Device Description:	LifeSpan Vascular Grafts are consisting of a base tube of expanded PTFE that is wrapped with PTFE tape for better strength. Externally supported grafts have a monofilament of PTFE wrapped over the tape for added crush and kink resistance. The stepped and tapered grafts have a small diameter end and a large diameter end. All models of the graft have a printed black orientation line consisting of "LeMaitre LifeSpan" printed repeatedly along the length of the graft. This 510k is to add an alternative ink for the printing the orientation line.

Intended Use:	• The LifeSpan ePTFE vascular grafts are indicated for use as a vascular prosthesis only. The grafts are intended for bypass or reconstruction of diseased or occluded blood vessels, or for arteriovenous shunts for blood access. The physician must evaluate each alternative method of treatment, discuss the risks and benefits with each patient, and decide whether to use a prosthetic vascular graft based upon all available factors. • Grafts with removable external monofilament support over the length of the graft are used in bypass or reconstruction of occluded or diseased vessels, where compression or kinking could jeopardize patency. • Grafts with external monofilament support in the middle of the graft may be used for the creation of an arteriovenous shunt for blood access; however, the graft must not be cannulated in the area of the external monofilament support. • Stepped and tapered grafts are used for the creation of arteriovenous shunts for blood access. Stepped and tapered configurations may reduce the risk of steal syndrome and high cardiac output.
Summary of Technological Characteristics:	LifeSpan Vascular Grafts are consisting of a base tube of expanded PTFE that is wrapped with PTFE tape for better strength. Externally supported grafts have a monofilament of PTFE wrapped over the tape for added crush and kink resistance. The stepped and tapered grafts have a small diameter end and a large diameter end.
Summary of Product Testing:	Biocompatibility test was performed for the alternative new ink.
Summary of Pre-clinical Study:	The biocompatibility of the device was tested per ISO10993-1.
Conclusion:	LeMaitre Vascular has demonstrated that the LifeSpan ePTFE Vascular Graft printed with the new ink is substantially equivalent to the predicate devices based on its indications for use and fundamental scientific technology.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

LeMaitre Vascular, Inc.
C/O Xiang Zhang,
Director of Regulatory Affairs
62 Second Avenue
Burlington, MA 01803

FEB 0 5 2013

Re: K130016
Trade/Device Name: LifeSpan ePTFE Vascular Graft
Regulation Number: 21 CFR 870.3450
Regulation Name: Vascular Graft Prosthesis
Regulatory Class: Class II
Product Code: DSY
Dated: January 2, 2013
Received: January 3, 2013

Dear Mr. Zhang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Matthew G. Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4: INDICATION FOR USE STATEMENT

510(k) Number (if known): K130016

Device Name: LifeSpan ePTFE Vascular Graft

Indications for Use:

The LeMaitre LifeSpan ePTFE vascular grafts are indicated for use as a vascular prosthesis only. The grafts are intended for bypass or reconstruction of diseased or occluded blood vessels, or for arteriovenous shunts for blood access.

Prescription Use_____X_____ and/or Over-The Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE ID NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K130016